

**DOCKET NO.: DIBIS-0012US.P1 (Counsel Docket No. 10449)****PATENT****REMARKS****I. Summary of Office Action**

Claims 1-49 were pending and under examination. In the Office Action mailed April 10, 2006 the Examiner makes a Restriction Requirement, restricting pending claims 1-49 into the following five groups:

Group I. (Claims 1-7, 22-24 and 27-39) drawn to identifying disease agents, classified in class 435, subclass 5.

Group II. (Claim 8) drawn to a bioinformatic method of primer design, classified in class 702, subclass 19.

Group III. (Claims 9-21) drawn to methods of epidemic surveillance, classified in class 435, subclass 6.

Group IV. (Claims 25-26) drawn to methods of identifying pharmacogenomic information, classified in class 536, subclass 6.

Group V. (Claims 40-49) drawn to primer pairs and amplicons, classified in class 536, subclass 24.3.

**II. Group Elections and Claim Cancellations**

Applicants elect, without traverse, to prosecute the claims of Group I. In an Amendment accompanying this response, Applicants have cancelled claims 1-26, 30 and 39-49 in order to further their business interests and the prosecution of the present application. Applicants reserve the right to prosecute the cancelled claims of Groups II, III, IV and V in one or more divisional applications.

With regard to the further restriction requirement applicable to all groups (page 4, last paragraph to page 5), the Office Action states that each of the groups named above is subject to a further restriction and requires election of one primer pair and the amplicon which is amplified by that primer pair. Applicants wish to point out that the claims of Group I are not claims to independent and distinct sequence inventions, and that primer pair sequence claims are not found in the independent or dependent claims of Group I. Thus Applicants cannot select a species within Group I as suggested by the Examiner. Applicants believe the application of

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the species request to Group I is in error. If the Examiner believes that a species selection within Group I is required, Applicants request that the Examiner identify which elements from which claims in Group I are the subject of the request. Without this guidance, Applicants are unable to respond to the request.

**IV. Claim Amendments**

Claim 27 has been amended to recite the steps of amplifying a plurality of segments of nucleic acid of the pathogen with a plurality of primer pairs to obtain a plurality of amplification products and determining the base compositions of at least two members of the plurality of amplification products to obtain a combination of base compositions wherein the combination of base compositions identifies the pathogen in the sample. Support for this amendment is found, for example, on pages 60 and 61 and in Figure 25.

Claim 29 has been amended to recite that the sample is a biological sample. This claim amendment is supported, for example, by original claim 27.

Claim 31 has been amended to recite that the sample is obtained from a human and to correct the antecedent basis to claim 27 and is fully supported, for example, by the original claims.

Claim 32 has been amended to recite that the plurality of primer pairs can include any combination of broad range survey, division wide, and drill-down primer pairs. Support for this amendment is found, for example, in original claim 1.

Claim 33 has been amended for the sake of clarity and antecedent basis and does not include modifications to claim elements.

Claim 34 has been amended to recite that the subspecies characteristic of the pathogen is identified from the base compositions of the plurality of drill-down primer pairs. Support for this amendment is found, for example, in Figure 25.

Claim 35 has been amended for the sake of clarity and antecedent basis and does not include modifications to claim elements.

Claim 36 has been amended to replace determination of molecular mass with determination of base composition. Support for this amendment is found, for example, in Figure 25.

Claim 37 has been amended for the sake of clarity to include the term "mass spectrometry" after each different type of mass spectrometry recited.

Claim 38 has been amended to recite that each member of each primer pair of the plurality of primer pairs hybridizes to nucleic acid encoding ribosomal RNA or a housekeeping

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gene. Support for this amendment is found, for example, on pages 57 and 58.

#### **V. New Claims**

Support for new claims 50, 64 and 85, wherein the housekeeping gene encodes a protein that participates in translation, replication, recombination, repair, transcription, nucleotide metabolism, amino acid metabolism, lipid metabolism, uptake, secretion, antibiotic resistance, virulence, or pathogenicity is found, for example, on page 14, lines 13-23 and on page 19, lines 10-12.

Support for new claims 51, 65 and 86, wherein the housekeeping gene is a polymerase, is found, for example, on page 37, line 21 and on page 64, lines 1-3.

Support for new claims 52, 67 and 87, wherein the pathogen, strain type, or etiologic agent is a previously unknown pathogen, strain type, or etiologic agent, is found, for example, on page 27, lines 10-12.

Support for new independent claim 53 is found, for example, on pages 60 and 61 and in Figure 25.

Support for new claim 54, 70, and 81, wherein the pathogen is a bacterium, a virus, a protozoan, a parasite, a mold or a fungus, is found, for example, in original claim 10.

Support for new claim 55, wherein the sample is a biological sample, is found, for example in original claim 1.

Support for new claim 56, 71 and 82, wherein the biological sample comprises blood, mucus, hair, urine, breath, sputum, saliva, stool, nail or tissue, is found, for example, in original claim 11.

Support for new claims 57 and 83, wherein the sample is obtained from a human, is found, for example, in original claim 13.

Support for new claims 58 and 76, wherein the plurality of primer pairs comprises broad range survey primers primer pairs, division-wide primers primer pairs, or drill-down primers primer pairs, or any combination thereof, is found, for example in original claim 1.

Support for new claim 59, wherein the pathogen comprises a sub-species characteristic, is found, for example in original claim 3.

Support for new claims 60 and 78, wherein the sub-species characteristic is a serotype, a strain type, a sub-strain type, a sub-species type, an emm-type, a bioengineered gene, a toxin gene, an antibiotic resistance gene, a pathogenicity island, or a virulence factor, is found, for example in original claim 4.

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Support for new claims 61, 72, and 79, wherein the base compositions are obtained from molecular masses of the plurality of amplification products determined by mass spectrometry, is found, for example, in original claims 1 and 7.

Support for new claims 62, 73 and 80, wherein the mass spectrometry is Fourier transform ion cyclotron resonance mass spectrometry (FTICR- MS), ion trap mass spectrometry, quadrupole mass spectrometry, magnetic sector mass spectrometry, time of flight (TOF) mass spectrometry, Q-TOF mass spectrometry, or triple quadrupole mass spectrometry, is found, for example in original claim 6.

Support for new claims 63, 74 and 84, wherein the primer pairs hybridize to nucleic acid encoding ribosomal RNA or housekeeping genes, is found, for example, in original claim 20.

Support for new claims 66, wherein the plurality of primer pairs comprises four or more primer pairs, is found, for example on page 55, lines 24-25.

Support for new claim 68 wherein the plurality of base compositions is associated with a known strain of the pathogen, thereby identifying the strain type of the pathogen is found, for example, in Figure 25.

Support for new independent claim 69 is found, for example, on page 29, lines 14-16.

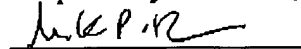
Support for new independent claim 75 is found, for example, in original claim 1.

Support for new claim 77, wherein a subspecies characteristic is determined from the base composition of an amplification product obtained with a drill-down primer pair is found, for example in original claim 3.

## **VI. Conclusions**

In view of the foregoing, Applicants submit that the claims of the instant application are in condition for allowance. The Examiner is invited to contact Applicants' undersigned representative if there should be any questions with regard to the claimed invention.

Respectfully submitted,



Mark P. Roach, Ph.D.  
Registration No. L0082  
Direct: (760) 603-2473

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ISIS Pharmaceuticals, Inc.  
1896 Rutherford Rd.  
Carlsbad, CA 92008  
Telephone: (760) 931-9200  
Facsimile: (760) 603-3820